DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Central Region

95096d

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 19, 2004

File # 05-NWJ-03

Mr. Steven Bosker
President and CEO
DiGiorgio Corp.
380 Middlesex Avenue
Carteret, New Jersey 07008

Dear Mr. Bosker:

We inspected your firm's White Rose Dairy refrigerated/ frozen warehouse facility, located at 215 Blair Road, Avenel, New Jersey on August 8, 12, 13, 16, 17, & 23, 2004. The inspection found that you have serious deviations from the Seafood HACCP regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6 (g), the failure of a processor to have and implement a HACCP plan that complies with this section, or to otherwise operate in accordance with the requirements of this Part renders the fishery products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug & Cosmetic Act (the Act) (21 U.S.C. §342(a)(4)). Accordingly, the deviations noted during the inspection cause your ready-to-eat (RTE) seafood products, including, but not limited to, seafood salads, jarred herring, and vacuum-packed smoked fish to be adulterated within the meaning of section 402(a) (4) of the Act, in that they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find this Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations found were as follows:

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, in order to comply with 21 CFR.123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of an identified food safety hazard." However, your firm's HACCP plan fails to list a critical limit at the receiving Critical Control Point (CCP). Your firm's HACCP plan, that is applicable to all your products, to control "pathogenic bacteria and organisms" fails to list a critical limit for transport conditions of products that have been in transit to your facility for longer than four hours. FDA does not consider monitoring product temperatures upon arrival as an adequate method of assuring that these products have been adequately chilled throughout transit/ shipment when transit times are greater than four hours. FDA recommends either monitoring critical limits associated with the adequacy of the cooling media upon receipt or some method of continuous time/temperature data record for the shipping containers or transport vehicle. As an example, [redacted] vacuum-packed smoked salmon products you receive are all shipped from suppliers in [redacted] and therefore have been in-transit in excess of four hours. Checking product temperatures on arrival will not identify fluctuations in temperatures that may have occurred over these extended transit times. Your current temperature monitoring process also does not specify that seafood items (transported less than four hours), especially ready-to-eat and histamine forming species, will be monitored for temperature. In addition, your method of using an infrared thermometer is not the method recommended by FDA because it does not determine the internal temperatures of the products, only the surface temperatures. FDA currently recommends that internal temperatures or their equivalents are monitored upon receipt.

- You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c) (4). However, while your firm's HACCP plan lists, as a critical limit at the storage CCP, "coolers set below [redacted] F and [redacted] F (for smoked fish items)," your plan does not list monitoring procedures to assure that the products are continuously maintained at these temperatures to prevent the occurrence of a food safety hazard (i.e., pathogen growth). FDA recommends continuous monitoring at refrigerated storage preferably using a continuous temperature monitoring device, with a visual check of the equipment daily. High temperature alarm systems with regular checks are adequate, and since you have temporary storage in trailers and/or reefer units, we recommend that you specify or identify each individual unit in your plan to ensure that all trailers and/or reefers are continuously monitored.

- You must fully implement the monitoring and recordkeeping procedures identified at the receiving CCP in your HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure listed at this CCP. Your HACCP plan lists a monitoring procedure of "all product is checked on arrival...using [redacted] On August 4th, 6th, and 9th, 2004, shipments that included ready-to-eat refrigerated seafood products were received by your firm. Your records did not include observations that document their temperatures. On June 28th, 2004, ready-to-eat histamine producing product (herring) was included in a shipment, but your firm did not record observations of the temperature of that product.

- You must take a corrective action when a deviation from a critical limit occurs, in order to comply with 21 CFR Part 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation, and that the cause the deviation is corrected. However, your firm did not take a corrective action when storage temperatures exceeded your critical temperature limit of [redacted]°F as listed in your HACCP plan. Specifically, on August 11, 2004, our investigator noted that the Weekend Refrigeration and Security Report indicated temperatures ranging from 50°F to 52.5°F. Your firm's management stated no corrective actions were taken to address the temperature issues.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/ or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations. You should include in your response documentation such as revised HACCP plan(s), revised monitoring procedures, copies of revised monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all deviations at your facility. You are responsible for ensuring that your facility operates in compliance with the Act, the Seafood HACCP regulation and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above.

Sincerely,

Douglas I. Ellsworth

Douglas I. Ellsworth
District Director
New Jersey District

CC: Joseph Fantozzi, Senior Vice President
White Rose Dairy
215 Blair Road
Avenel, New Jersey 07001